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02/05/24

First UK Patients Receive Experimental Messenger RNA Cancer Therapy + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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First UK Patients Receive Experimental Messenger RNA Cancer Therapy

The Guardian reported:

> A revolutionary new cancer treatment known as mRNA therapy has been administered to patients at Hammersmith Hospital in West London. The trial has been set up to evaluate the therapy's safety and effectiveness in treating melanoma, lung cancer and other solid tumours.
>
> The new treatment uses genetic material known as messenger RNA — or mRNA — and works by presenting common markers from tumors to the patient's immune system.
>
> A number of cancer vaccines have recently entered clinical trials across the globe. These fall into two categories: personalized cancer immunotherapies, which rely on extracting a patient's own genetic material from their tumors; and therapeutic cancer immunotherapies, such as the

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mRNA therapy newly launched in London, which are "ready-made" and tailored to a particular type of cancer.

The primary aim of the new trial — known as Mobilize — is to discover if this particular type of mRNA therapy is safe and tolerated by patients with lung or skin cancers and can shrink tumors. It will be administered alone in some cases and in combination with the existing cancer drug pembrolizumab in others.

Feds Plan Fall Vax Push for Older Americans

Politico reported:

> Federal officials are asking groups representing older Americans what they can do to improve COVID-19 vaccine uptake during the next respiratory illness season, Chelsea and Daniel report. This comes after a lackluster number of long-term care residents got the updated COVID shot this season.
>
> The meeting, billed as a White House Long-Term Care Leadership Summit, was one of a series of conversations HHS Secretary Xavier Becerra has hosted with long-term care facilities to remind them of their duty to offer residents the shots. During those meetings, groups asked the administration for more support in persuading residents to get vaccinated.
>
> In a statement to Pulse, Dr. David Gifford, American Health Care Association's chief medical officer, highlighted the "significant, systemic challenges with vaccine reluctance that requires a collective endeavor by public health officials, other health care providers, and the public to overcome."

An OxyContin Advertiser Will Pay $350 Million in the First-Ever Opioid Marketing Settlement

CNN Business reported:

> For the first time, an advertising company that worked on Purdue Pharma's OxyContin account has settled a lawsuit that accused it of falsely marketing opioids as safe.
>
> Publicis, a French marketing company, agreed to pay $350 million within the next two months and will not take on any more opioid clients, according to New York Attorney General Letitia James. She and Colorado Attorney General Phil Weiser led the settlement negotiations, which included a consortium of eight other states.
>
> "For a decade, Publicis helped opioid manufacturers like Purdue Pharma convince doctors to overprescribe opioids, directly fueling the opioid crisis and causing the devastation of communities nationwide," said James in a statement. "No amount of money can compensate for lives lost and addiction suffered, but with this agreement, Publicis will cease their illegal behavior."
>
> The "Evolve to Excellence" marketing scheme barraged doctors with messages that falsely claimed OxyContin deterred addiction and abuse and pushed physicians to increase patients' doses — even when not medically appropriate, James said. Publicis created the advertisements, pamphlets and brochures for the campaign.

A Non-Opioid Painkiller Is Just What America Needs

Bloomberg reported:

> The likely arrival of a new kind of pain pill—one that doesn't carry the risk of addiction — feels like a rare moment of lightness amid the relentlessly heavy news about opioids in the US.
>
> Vertex Pharmaceuticals' non-opioid treatment, which could get regulatory approval as soon as late 2024, could provide a much-needed option to

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doctors trying to treat serious pain.

But there's a wrinkle. Data this week suggests Vertex's new pill, dubbed VX-548, works roughly as well as, but not better than (and, in one study, slightly worse than) opioids in treating acute pain. That has sparked a debate among some pain experts and analysts about its commercial viability. Will doctors — should doctors — choose a pricey new drug over dirt-cheap opioids? Will insurers pay for it?

Millions of people in the U.S. have an opioid use disorder, an epidemic rooted in the systematic overprescribing of addictive painkillers. A robust body of data suggests that about 3%-5% of those who start taking an opioid will go on to develop an addiction. That might sound insignificant. But there are tens of millions of prescriptions for opioids written every year.

Medicare Drug Price Negotiations Kick Off With Price Offers on These 10 Drugs

USA TODAY reported:

Aiming to make life-saving medications more affordable, the Biden administration on Thursday sent offers to drug companies that make 10 widely prescribed drugs for older Americans.

Thursday's effort was the opening salvo over Medicare drug price negotiations. Department of Health and Human Services officials did not reveal how much the government's price negotiators initially offered to pay pharmaceutical companies that make drugs to treat conditions such as heart failure, stroke, diabetes and autoimmune disease.

The drugs include Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara and the insulins Fiasp and NovoLog.

Biden administration officials said the initial offers will start a back-and-forth with drug manufacturers over the spring and summer months. Final prices for the first batch of drugs will be made public on Sept. 1, and the negotiated prices will take effect in January 2026.

U.S. Permanently Eases Some Opioid Treatment Restrictions

Axios reported:

Pandemic-era policies that made it easier for patients to receive opioid addiction treatment will continue permanently, the Biden administration announced this week.

Why it matters: The changes mark the first time in 20 years the federal government has updated rules governing clinics that provide medication-assisted treatment for opioid use disorder. Years into the nation's opioid crisis, only about 1 in 5 people with opioid addiction received medication to treat it in 2021.

Details: The finalized policy will allow patients to take home doses of the opioid addiction treatment methadone. Patients will also be able to start on methadone or buprenorphine, another opioid addiction treatment medication, via telehealth.

Of note: The rule ends a requirement that patients have a yearlong history of opioid misuse before getting admitted to an opioid treatment clinic.

Doctor Who Prescribed More Than 500,000 Opioid Doses Has Conviction Tossed

Reuters reported:

A Virginia doctor who prescribed more than 500,000 opioid doses in less than two years had his conviction and 40-year prison sentence thrown out by a federal appeals court on Friday because the jury instructions misstated the law.

The 4th U.S. Circuit Court of Appeals in Richmond, Virginia also ordered a new trial for Joel Smithers, 41, who has been serving his sentence in an Atlanta prison.

Copycat Eye Drops? FDA Issues Warning for Contaminated Eye Drops That Can Cause Infections

USA TODAY reported:

The U.S. Food and Drug Administration (FDA) has issued yet another warning in the long list of eye drop-related recalls and alerts announced over the last year.

This time, the organization is cautioning consumers to double-check their eye drops for authenticity, as a number of copycats have made their way to the U.S.

The FDA offered several examples of counterfeit products, which have been packaged to look strikingly similar to authentic Lumify artificial tears produced by Bausch + Lomb. According to the announcement, these off-brand versions are not approved for use and should not be available for sale in the U.S. at all, as they pose a risk of infection, irritation, or injury.

The FDA's warning cited three specific counterfeit products posing as a legitimate product, Bausch + Lomb's Lumify drops: South Moon, Rebright and FivFivGo.

Roche Shuffles Early Stage Pipeline as It Joins Obesity Rush

BioPharma Dive reported:

Roche is reshaping its early-stage pipeline of experimental drugs, jettisoning eight drug candidates in neurological conditions and oncology as it makes room for a set of obesity treatments it gained with its $2.7 billion acquisition of Carmot Therapeutics.

The Swiss drugmaker is dropping two Alzheimer's drugs, including the longtime asset crenezumab; a drug it had tested in both autism and post-traumatic stress disorder; and two projects for rare neurological disorders. Three Phase 1 cancer candidates also were shelved.

The eight drugs removed are being replaced by an equal number, spread across obesity, cancer and autoimmune disorders, to "increase the overall portfolio value and speed up development," Roche said in a presentation alongside its fourth quarter and full-year earnings announcement.

Valneva Sells Regulatory 'Fast Pass' for $103 Million

BioPharma Dive reported:

Vaccine maker Valneva on Monday said it has sold a priority review voucher to an undisclosed buyer for $103 million.

The voucher, a sort of regulatory fast pass, was awarded to Valneva by the Food and Drug Administration alongside its Nov. 9 approval of Ixchiq, the company's vaccine to prevent disease caused by the chikungunya virus.

Valneva plans to invest the cash into Phase 3 testing of a Lyme disease vaccine it's co-developing with Pfizer, and into additional trials of Ixchiq.

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